

Application Serial No. 08/385,206
Attorney's Docket No. 001560-223

REMARKS

Entry of the foregoing, reconsideration and reexamination of the subject application pursuant to 37 C.F.R. §1.112 are respectfully requested.

Applicants note with appreciation the indication by the Examiner that the restriction made in the parent application has been withdrawn. Claims 1-28 are thus being examined.

The Abstract has been objected to because it is in the form of two paragraphs. In view of the submission of a new Abstract having only one paragraph, withdrawal of this objection is believed to be in order.

In addition, the objection to the disclosure based on several informalities should be withdrawn in view of the present amendment to correct those informalities.

The specification has been objected to under 35 U.S.C. §112, first paragraph, as allegedly failing to provide an enabling disclosure. This objection is respectfully traversed.

More specifically, the Examiner states that it is unclear in the second method of obtaining a hop extract (Example 2), how the first and second separations are effected. Applicants note that in both the first and second separation steps, extracted products are separated as a liquid, while an extraction medium, i.e., carbon dioxide, is maintained in a supercritical or subcritical state. This would be clear to the skilled artisan by reference to the example and, in particular, to the conditions set forth therein.

Application Serial No. 08/385,206
Attorney's Docket No. 001560-223

The specification has further been objected to, and claims 2, 4 and 6 have been rejected under 35 U.S.C. §112, first paragraph, as failing to provide a proper antecedent basis for the claimed subject matter. This objection is respectfully traversed. More specifically, the Official Action states that the specification does not recite that the pressure can be higher than 100 kg/cm². Applicants note, however, that support may be found in the specification at page 5, lines 23-25; page 6, lines 6-9 and 25-28; and page 7, lines 14-17. Withdrawal of this objection is thus respectfully requested and believed to be in order.

Claims 9-12, 15-18, 21-23 and 26-28 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. There is allegedly no antecedent basis for the phrase "the step of the wort boiling" or "the whirlpool rest step" as recited in the claims. These rejections are now moot in view of the amendments to the claims. Withdrawal of this rejection is thus respectfully requested.

Prior to addressing the prior art rejections of record, a complete understanding of Applicants' invention is believed to be necessary. Applicants' invention relates to a method of obtaining hop extract using supercritical or subcritical carbon dioxide as the solvent. Applicants have found that if the pressure of the subcritical or supercritical carbon dioxide is set to 80 - 100 kg/cm², it is possible to obtain a hop extract which contains a large amount of essential oil components which impart aromaticity to the beer. Alternatively, the hop may be extracted by first extracting the bitter components and the essential oil components together with the extraction pressure at over 100 kg/cm², and

Application Serial No. 08/385,206
Attorney's Docket No. 001560-223

performing separation in two stages comprising the removal of the bitter components in a first separation tank followed by obtaining a hop extracts in a second separation tank. The extracts obtained by the methods according to the present invention contain a large amount of essential oil in proportion to the bitter components. As a result, the amount of essential oil to be added to the wort or beer may be determined with disregard to the slightly present bitter components, making it possible to control the aromaticity of the beer.

Furthermore, by adding to a wort a product comprising a mixture of essential oil extract and hop extract residue (product containing essential oil components), the efficient and effective migration of the hoppy aromatic components to the wort is made possible. Due to the interaction between the essential oil extract and the hop extract residue, when the product containing essential oil components is added to the wort, the essential oil components gradually migrate to the wort from the product containing essential oil components, with no dispersion of the essential oil components due to heat, making it possible to obtain highly aromatic wort.

In the conventional process of beer manufacturing, the hops are added during the boiling of the wort and decanted off after the whirlpool rest after boiling. The hop extract residue according to the present invention is sometimes added to the wort in exactly the same manner; however, there is absolutely no adverse effect caused by the addition of the hop extract residue, such as changes in the flavor of or deterioration of the wort. Beer obtained using the highly aromatic wort obtained in this manner in the conventional method of beer manufacturing has a pleasant, flowery hop fragrance, while

Application Serial No. 08/385,206
Attorney's Docket No. 001560-223

there is none of the undesirable strong grassy odor from the hops or the bitterness deep in the throat caused by α -acids. Therefore, beer may be obtained with a refreshing, deep-bodied hop flavor.

Now turning to the prior art rejections of record, claims 1 and 3 have been rejected under 35 U.S.C. §102(b) as being clearly anticipated by Vitzthum et al (U.S. Patent No. 4,204,409). This rejection is respectfully traversed.

It is noted that for a prior art reference is anticipatory only if every element of the claimed invention is disclosed in a single item of prior art in the form literally defined in the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986), *cert denied*, 480 US 947 (1987). In the presence case, the criteria for such a rejection is not satisfied. At the very least, Vitzthum et al fails to disclose or even suggest a process for production of an essential oil-rich hop extract, which comprises "extracting hops with supercritical or subcritical carbon dioxide solvent at a pressure of 80 to 100 kg/cm² to obtain a carbon dioxide extract" (77 to 97 atm¹). Instead, Vitzthum et al discloses a process wherein "the entire soft resin portion and the essential oils of the hops, but less than 1 % of the hard resin portion, can be extracted by working at extraction pressures of 100 to 200 excess at." (col. 3, lines 19-23). The reference further teaches a method for extracting "the entire alpha-acids and the essential oils but less than 100% of the beta-acids contained in the hops and less than 100% of the hard resin portions, are extracted by working at extraction pressures of 100 - 220 excess at. and separating the

¹ 1 atm = 1.0333 kg/cm²

Application Serial No. 08/385,206
Attorney's Docket No. 001560-223

extract further by subjecting it to an additional supercritical extraction at pressures of 100 - 150 excess at." (col. 3, lines 25-31). The reference thus neither discloses nor even suggests the presently claimed process or product obtained therefrom, wherein the extraction is at a pressure of 80 to 100 kg/cm². Even in Example 1 cited in the Official Action, the extraction pressure is 315 atmospheres, which would clearly teach away from the claimed range.

Nor does the reference disclose or even suggest the beneficial results obtained from such a process. As stated in the present specification, "[t]he present invention was completed upon the discovery that a method of obtaining hop extracts containing a large amount of specific essential oil components which impart aroma to hops (hereunder referred to as 'essential oil-rich hop extract' or 'essential oil extract')" (page 5, lines 11-16). The present invention further obtains extracts "containing a large amount of essential oil in proportion to the bitter components" (page 20, lines 28-30). In contradistinction, the process of Vitzthum et al produces "extracts with particularly high alpha-acid contents" (*see*, col. 3, lines 16-17). The process of Vitzthum et al is aimed at extracting the soft resin (α -acids) and essential oils, excluding hard resin (*see*, col. 3, lines 24-31). By contrast, the process of the present invention aims to exclude the α -acids. Vitzthum et al thus fails to teach extracting at a pressure of 80-100 kg/cm² and that by operating at such a pressure, extraction of a hops extract containing α -acid is prevented.

The specification further distinguishes the claimed method from those known in the art such as Vitzthum et al in that prior art processes extract from hops using

Application Serial No. 08/385,206
Attorney's Docket No. 001560-223

supercritical or subcritical carbon dioxide at a pressure of 60-400 kg/cm², while using a pressure of 20-150 kg/cm² in the separation tank. By contrast, in the method of the invention, "the extraction from the hops is controlled by maintaining the pressure of the carbon dioxide in the extraction tank in a range of 80 - 100 kg/cm², to obtain a hop extract containing a large amount of specific essential oil components" (page 9, line 34 to page 10, line 2). Such control is in no way even alluded to in Vitzthum et al.

Withdrawal of the rejection of the claims under 35 U.S.C. §102(b) is thus respectfully requested and believed to be in order.

Claims 2 and 4 have been rejected under 35 U.S.C. §103 as being unpatentable over Vitzthum et al in view of Wheldon et al (U.S. Patent No. 4,282,259). This rejection is respectfully traversed.

According to the Official Action, Vitzthum et al fails to disclose the separation of the hop extract into different fractions. Wheldon et al is thus cited as disclosing a process whereby hop extracts are produced by subjecting the hop material to the solvent action liquid CO₂, which action extracts the hop acids and oils from the hop material. It is concluded that it would have been obvious to separate the hop extract of Vitzthum et al into the two fractions as done by Wheldon et al since it is useful to have an extract that has a high concentration of hop oils.

In establishing a *prima facie* case of obviousness, it is incumbent upon the Patent Office to provide a reason *why* one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed

Application Serial No. 08/385,206
Attorney's Docket No. 001560-223

invention. To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as whole or from the knowledge generally available to one of ordinary skill in the art and not from Applicants' disclosure. *Ex parte Nesbit*, 25 USPQ2d 1817, 1819 (BPAI 1992). In the present case, no such motivation exists. Vitzthum et al is directed to a "[p]rocess for extraction of hops utilizing supercritical gases such as carbon dioxide" (Abstract). By contrast, Wheldon et al is directed to a method of preparing an extract using liquid carbon dioxide, which is not supercritical or subcritical. In fact, Wheldon et al *distinguishes* itself as an *improvement* over methods using supercritical carbon dioxide, by stating as follows at col. 4, lines 45-51:

This is a considerable advantage over the systems using super critical carbon dioxide to extract matter since, with a system in which carbon dioxide is always super critical in respect to pressure, temperature or both, it is impossible to vent any volatile impurities which are present in the system.

In view of the above, one skilled in the art would not combine Vitzthum et al, directed to a process using supercritical carbon dioxide, with Wheldon et al, stating the disadvantages of using supercritical carbon dioxide. In fact, Wheldon et al specifically teaches away from such a combination.

Furthermore, even if the proposed combination of references was proper, a *prima facie* case of obviousness would still not be achieved. More specifically, the combination of references fails to disclose or suggest "separating bitter components from the carbon dioxide extract at a pressure between 100 kg/cm² and said extraction pressure" followed by "separating an essential oil-rich hop extract from the carbon dioxide extract at

Application Serial No. 08/385,206
Attorney's Docket No. 001560-223

a pressure of lower than 100 kg/cm²". Neither of the references teaches such process steps for obtaining an essential oil-rich hop extract. More specifically, the combination of references fails to teach that after first extracting hops with supercritical or subcritical carbon dioxide solvent at an extraction pressure of higher than 100 kg/cm², the carbon dioxide extract obtained may be separated from the bitter components by operating at a pressure between 100 kg/cm² and the extraction pressure. Nor do the references disclose or even suggest that the essential oil-rich hop extract may then be separated from the carbon dioxide extract by operating at a pressure of lower than 100 kg/cm².

Wheldon et al merely states that hop oils can be isolated separately from the bitter principles. However, the reference fails to disclose or even suggest how the hop oils can be isolated separately from the bitter principles. Similarly, the reference states that the proportion of the hop oils contained in the extracted matter can be varied. Wheldon et al fails to describe how to vary the proportion. Furthermore, while stating that the concentration in the liquid carbon dioxide in the secondary path of the heat exchanger gradually builds up, the reference does not suggest the operation necessary to build up the concentration. Wheldon et al in combination with Vitzthum et al thus fails to teach Applicants' claimed invention wherein the bitter components are separated in the first separation step and the essential oil-rich hop extract is separated in the second separation step, by means of the claimed pressure ranges.

Application Serial No. 08/385,206
Attorney's Docket No. 001560-223

In view of the above, even if the combination of references was proper, a *prima facie* case of obviousness would not be established. Withdrawal of the rejection of the claims is thus respectfully requested and believed to be in order.

Claims 5 to 28 have also been rejected under 35 U.S.C. §103 as being unpatentable over Vitzthum et al in view of Wheldon et al and in further view of Todd, Jr. et al (U.S. Patent No. 4,647,464). This rejection is respectfully traversed.

Todd, Jr. et al is cited for teaching the absorption of a hop oil extract onto fumed silicon dioxide to reduce the amount of aroma which is lost during the boiling of the wort, which later is fermented to produce a finished beer. It is asserted that Applicants mix their hop extract with their hop residue to obtain a product which functions in the same manner as that of Todd, Jr. et al.

This assertion is in error. Todd, Jr. et al is directed to the use of fumed silicon dioxide for absorbing hop flavors. Todd, Jr. et al is thus unrelated to mixing an essential oil-rich hop extract with a hop extract residue as presently claimed. Todd, Jr. et al is unrelated to the claimed products and processes. Todd, Jr. et al thus fails to overcome even the deficiency in the combination of Vitzthum and Wheldon for which it is cited.

As stated above, Applicants believe that the combination of Vitzthum and Wheldon is improper. Moreover, even if the combination was proper, the claimed invention would not be achieved since the neither of the references teach either:

- (1) extracting hops with supercritical or subcritical carbon dioxide solvent at an extraction pressure of higher than 100 kg/cm² to obtain

Application Serial No. 08/385,206
Attorney's Docket No. 001560-223

a carbon dioxide extract and a hop extract residue; and separating an essential oil-rich hop extract from the carbon dioxide extract; or

- (2) extracting hops with supercritical or subcritical carbon dioxide solvent at an extraction pressure of higher than 100 kg/cm² to obtain a carbon dioxide extract and a hop extract residue; separating bitter components from the carbon dioxide extract at a pressure between 100 kg/cm² and said extraction pressure; and then separating an essential oil-rich hop extract from the carbon dioxide extract at a pressure of lower than 100 kg/cm².

As previously stated, neither reference discloses or even suggests such processes. Todd, Jr. et al, directed to adsorbing hop flavors on fumed silicon dioxide, fails to overcome these deficiencies in the primary and secondary references.

Nor does the combination of references disclose or suggest the beneficial results obtained from such products and processes. As described in the specification at from page 1, line 25 to page 2, line 2, storage stability of whole hops is low due to oxidative degradation, even if the hops is dried. This drawback can be overcome by extracting whole hops and storing the extract comprising an essential oil of the hops. However, although most of the essential hop oil is transferred to the extract, some part of the essential oil remains in the extract residue. Therefore, if the extract alone is added to wort, the portion of the essential oils remaining in the extract residue is not added to the wort. To compensate for this drawback, the use of the extract residue while still obtaining a portion of the essential oil which was not transferred to the extract is preferable. While hop is not stable, both the extract and the extract residue are stable during storage if they are stored separately. This is one reason for use of the extract residue.

Application Serial No. 08/385,206
Attorney's Docket No. 001560-223

Another reason for use of the extract residue is that if the extract is added to wort, and the wort is then boiled, a part of essential oil contained in the extract is then evaporated because the essential oil is highly volatile. By contrast, if the extract is added to the wort after the wort is boiled, the extract is not heated. However, heating of the essential oil is necessary to improve the aroma of the beer. To overcome these difficulties, a product comprising an extract residue to which an extract is absorbed is added to the wort prior to boiling the wort, followed by boiling the wort. To do so, the evaporation-off of the essential oil is prevented, and improvement of the aroma of the beer is still achieved. Such beneficial results of the present invention (as evidenced by Table 5), however, are not taught by the combination of references.

The rejection of the claims under §103 is thus improper. Withdrawal is respectfully believed to be in order.

In view of the above, further and favorable action in the form of a Notice of Allowance is respectfully requested. Such action is believed to be in order.

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Application Serial No. 08/385-206
Attorney's Docket No. 001560-223

In the event that there are any questions relating to this amendment or to the application in general, it would be appreciated if the Examiner would contact the undersigned attorney to expedite prosecution of the application on the merits.

Respectfully submitted,

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